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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,406

08/15/2003

Richard L. Quick

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EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

02/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/642,406	Applicant(s) QUICK ET AL.	
	Examiner Fangemonique Smith	Art Unit 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7-10,15,16,19,21,71,74,76-85,87 and 89-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-10,15,16,19,21,71,74,76-85,87 and 89-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/15/08</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office Action is responsive to the Request for Continued Examination filed on November 26, 2007. The Examiner acknowledges the cancellation of claims 73 and 75; amendment of claims 1, 8, 16, 21, 71, 74, 77, 83-85 and 89; and the addition of claims 96-100. Claims 1, 7-10, 15, 16, 19, 21, 71, 74, 76-85, 87 and 89-100 are pending. All claim objections and 112 rejections made in the Office action dated August 27, 2007 have been overcome with amendments made to the claims.

#### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities:

- a. At lines 10 and 11 of claim 1, it is suggested to modify the limitation "one outer tissue cutting edge, which a tissue receiving opening" to read -- one outer tissue cutting edge, with a tissue receiving opening--.

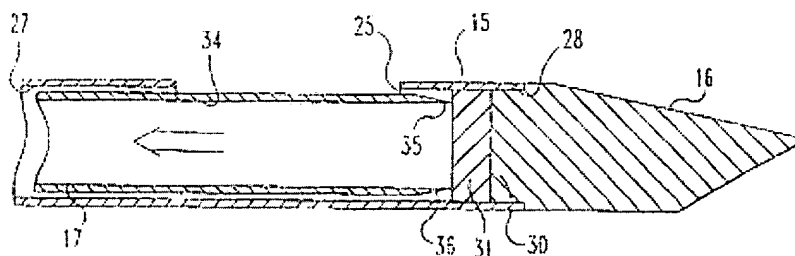
Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In regard to claim 1, 7-10, 15, 16, 19, 71, 74, 83-85, 87, 89 and 97-100, Miller et al. disclose a tissue biopsy device (10) for accessing and collecting a tissue specimen from a target site within a patient. The biopsy device comprises an elongated probe member (15), which has a proximal end configured to be secured to a drive and an inner lumen (27) extending along a longitudinal axis. Miller et al. describe the probe further having a penetrating distal tip (16) and an aperture (25) proximal to the penetrating distal tip configured to receive tissue from the target site. The Miller et al. device further includes an elongated tissue cutting member (17), which is disposed within the elongated probe member (15), which has at least one tissue cutting edge (35, 36). The at least one cutting edge creates an angle with respect to the longitudinal axis less than 90 degrees (Fig. 5) and engages a tissue cutting edge (35) of the tissue cutting member.



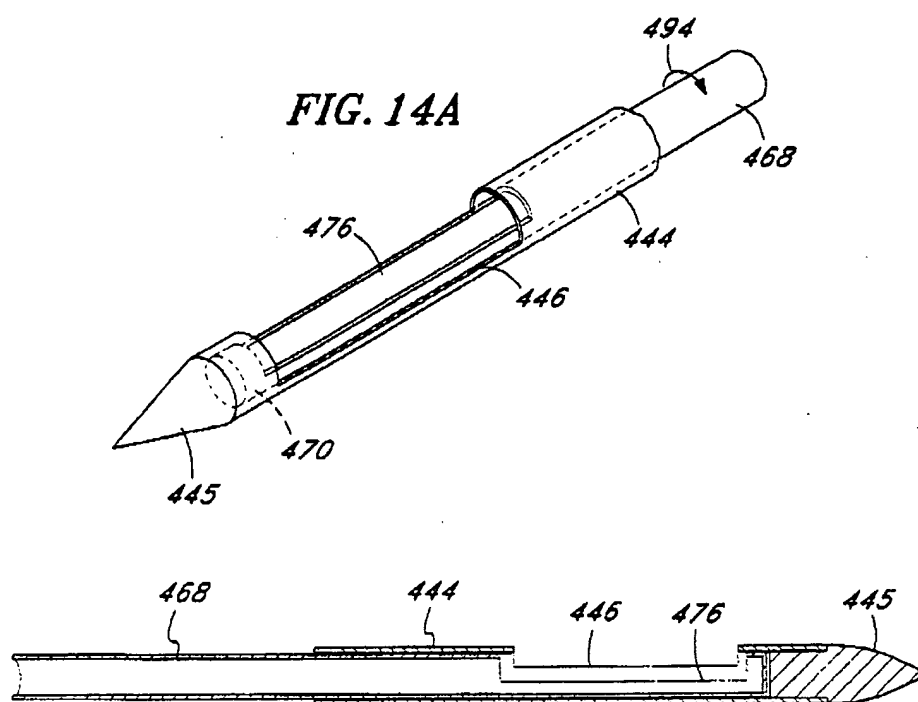
**Fig. 5**

The tissue cutting member (17) has an inner lumen (34), which is configured to be operably connected to at least one drive unit (22). The inner lumen (34) of the tissue cutting member (17) is further configured to access a vacuum source to transport a tissue specimen through the inner

lumen (34) to a tissue collector (55) in fluid communication with the inner lumen. The aperture (25) of the probe (15) has at least one longitudinally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose a tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient. Miller et al. disclose the inner lumen of the tissue cutting member (17) is configured to access a vacuum source (150) to transport a cut tissue specimen to a tissue collection trap (55) in fluid communication with the inner lumen of the tissue cutting member. The aperture (25) of the probe (15) has at least one longitudinally distally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled needle-like tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose the probe comprising an outer member (75), which has a proximal tubular portion (15) configured to be releasably secured to a drive housing (70) and an inner lumen (17) extending therein. A tissue penetrating distal tip (16) is disclosed by Miller et al. The device has an open section (25) proximal to the penetrating distal tip (16) and a supporting strut (30) extending from the penetrating distal tip to the proximal tubular portion (15). Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue

specimen cut by the tissue cutting member. The tissue cutting member (17) is further connected to a drive unit (20) to move the tissue cutting member (17) within the inner lumen of the tissue accessing cannula. The cutting edge (35) of the device is parallel to a longitudinal axis of the tissue cutting member (17) and the tissue cutting member moves longitudinally in a reciprocating motion about the longitudinal axis (col. 8, lines 1-45). The reciprocating motor is capable of moving the tissue cutting member in a reciprocal longitudinal movement of between about 0.01 inch and about 0.2 inch. The tissue accessing cannula (43) has a distal end (28) seated against a proximal surface of the tissue penetrating distal tip (16) of the outer member. The tissue accessing cannula is operably secured to a drive unit (20) in the drive housing (70) to rotate the tissue receiving cannula (50). In addition, Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member (17). The tissue cutting member (17) is rotatably disposed within the inner lumen of the tissue accessing cannula (34) with a longitudinal axis and a longitudinal tissue cutting edge oriented at an angle with respect to the longitudinal axis. Miller et al. further disclose the tissue cutting member having a non-cutting surface, which defines a tissue receiving aperture along with the tissue cutting edge parallel to the tissue cutting member. The cutting edge of the tissue cutting member further includes a leading distal cutting edge portion and an opposing trailing proximal cutting edge portion. Although Miller et al. disclose a tissue cutting edge having an angle less than 90 degrees with respect to the longitudinal axis, the Miller et al. do not specifically disclose having a longitudinal slot which opens to the tissue receiving

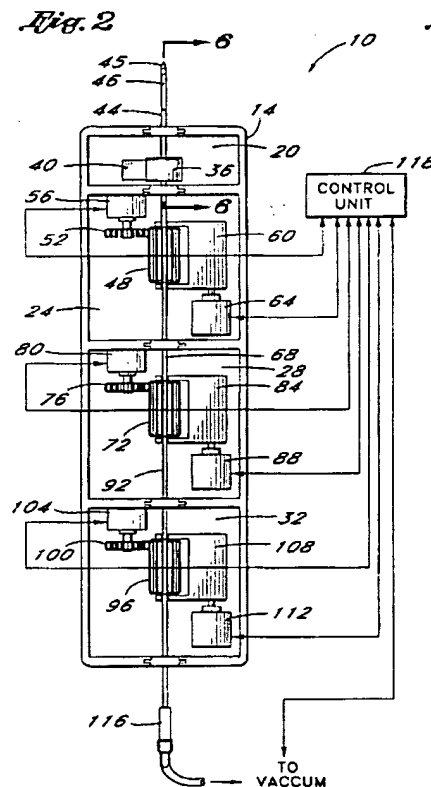
opening as described in the amended claims. Burbank et al. disclose a method and device for the automated biopsy and collection of soft tissue. The device disclosed by Burbank et al. includes an elongated probe member (444) which has a longitudinal axis and both a proximal and distal end. The proximal end of the elongated member is configured to be secured to a drive (464) and the elongated probe member has an inner lumen extending therein. The distal end includes a penetrating distal tip (445) and the probe further includes an aperture (446) configured to receive tissue from a target area within a patient. An elongated tissue cutting member (468) is disposed within the elongated probe member (444) as shown below.



**FIG. 14B**

The elongated tissue cutting member has a beveled distal tip with at least one outer tissue cutting edge and a tissue receiving opening with an inner lumen therein (Figure 6A, 6B). Burbank et al.

disclose the inner lumen of the tissue cutting member being an open pathway in fluid communication with the tissue receiving opening. Figure 14A and Figure 14B both illustrate the distal wall of the elongated tissue cutting member having a longitudinally oriented slot with a leading and trailing edge and opens to the tissue receiving opening. A drive unit (88) controls the movement of the tissue cutting member and positions the outer tissue cutting edge of the tissue cutting member to sever tissue at the target site (col. 18, lines 9-46). A vacuum source is connected to the Burbank et al. device (Figure 2).



Burbank et al. disclose having drivers which move the tissue cutting member of the device in an oscillating motion about the longitudinal axis. The device further includes longitudinal movement. It would have been obvious to one having ordinary skill in the art at the time the



Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by Miller et al., to include a tissue cutting member with a longitudinally oriented slot, similar to that disclosed by Burbank et al., to provide a larger receiving area to obtain a larger tissue sample.

5. Claims 77-82 and 90-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S Patent Number 6,758,824) in view of Burbank et al. (U.S. Patent Number 5,526,822) and in further view of Majlessi (U.S Patent Number 5,871,454).

In regard to claims 77-82 and 90-95, the combined references of Miller et al. and Burbank et al. disclose the features of the Applicant's invention as described above. The combined references do not disclose a second and third slot opening into the longitudinally oriented slot in a wall of the tubular member. Majlessi discloses a percutaneous excisional biopsy device having a plurality of tissue cutting members radially spaced about the longitudinal axis and strategically positioned at a target site to obtain multiple tissue samples. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by the combined references of Miller et al. and Burbank et al., to include multiple slotted wall sections of the tubular member, similar to that disclosed by Majlessi, to provide a mechanism which allows collection of multiple samples, while maintaining the functionality of the device.

*Response to Arguments*

6. Applicant argues the prior art reference do not include features of Applicant's invention as amended, Examiner submits Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

*Brian Smith*  
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10/3736